

UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

AMERICAN HOSPITAL
ASSOCIATION, et al.,

Plaintiffs

v.

ROBERT F. KENNEDY, JR.,
SECRETARY OF THE
UNITED STATES DEPARTMENT
OF HEALTH AND HUMAN
SERVICES, *et al.*,

Defendants

No. 2:25-cv-00600-LEW

ORDER ON MOTIONS TO INTERVENE

In a lawsuit challenging agency action under the Administrative Procedure Act, several pharmaceutical manufacturers move to intervene in support of the agency's action. Because the pharmaceutical manufacturers fail to demonstrate that the government will not adequately represent their interests in defending against the lawsuit, the court denies their motions. However, the Court will permit the pharmaceutical manufacturers to participate as amici curiae.

BACKGROUND

On December 1, 2025, the American Hospital Association (AHA) and the Maine Hospital Association (MHA), along with several of AHA's and MHA's members, (collectively, Plaintiffs) filed a complaint and a motion for temporary restraining order,

seeking to enjoin the implementation of a new federal drug pricing program, the 340B Rebate Model Pilot Program (the Pilot Program). Compl. for Decl. and Inj. Relief (ECF No. 1); Mot. for TRO (ECF No. 3). Plaintiffs allege that Defendants' promulgation of the Pilot Program violates the Administrative Procedure Act (APA) and ask this Court to declare the program unlawful under § 706 of the APA. Compl. ¶¶ 34-39, 52-62, 130-175.

On December 10, 2025, several pharmaceutical manufacturers (hereafter, "Movants") moved to intervene in this action. AbbVie Inc.'s and Pharmacyclics LLC's Mot. to Intervene (ECF No. 36) ("AbbVie Mot."); AstraZeneca Pharmaceuticals LP's Mot. to Intervene (ECF No. 39) ("AstraZeneca Mot."); Pharmaceutical Research and Manufacturers of America Mot. to Intervene (ECF No. 45) ("PhRMA Mot."); Boehringer Ingelheim Pharmaceuticals, Inc.'s and Novo Nordisk Inc.'s Mot. to Intervene (ECF No. 50) ("Novo Nordisk Mot."). Plaintiffs have opposed the motions. Pls.' Omnibus Opp'n to the Mots. to Intervene (ECF No. 76) ("Pls.' Opp'n"). Defendants have taken no position. Defs.' Position on Mot. to Intervene (ECF No. 74). Movants assert that they are entitled to intervene as a matter of right to represent what they claim are substantial and distinct interests. AbbVie Mot. at 5-9; AstraZeneca Mot. at 2-3; PhRMA Mot. at 2-6; Novo Nordisk Mot. at 4-9. Alternatively, Movants seek permissive intervention, arguing their intervention will not unduly delay or prejudice the adjudication of Plaintiffs' or Federal Defendants' rights. AbbVie Mot. at 9-10; AstraZeneca Mot. at 2-3; PhRMA Mot. at 6-7; Novo Nordisk Mot. at 10.

Plaintiffs oppose Movants' intervention, contending they have no right to intervene to protect contingent interests adequately represented by Federal Defendants. *Pls.' Opp'n*

at 2-8. As to permissive intervention, Plaintiffs aver Movants' intervention would complicate and delay proceedings without adding value to the Court's consideration of Federal Defendants' or Plaintiffs' arguments in this case. *Id.* at 8-10. Plaintiffs consent to the Court permitting Movants to participate as amici curiae, however. *Id.* at 10.

DISCUSSION

Under Federal Rule of Civil Procedure 24(a)(2), “[o]n timely motion, the court must permit anyone to intervene who . . . claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant’s ability to protect its interest, unless existing parties adequately represent that interest.” Fed. R. Civ. P. 24(a)(2). “[A] would-be intervenor must demonstrate that: (i) its motion is timely; (ii) it has an interest relating to the property or transaction that forms the foundation of the ongoing action; (iii) the disposition of the action threatens to impair or impede its ability to protect this interest; and (iv) no existing party adequately represents its interest.” *Ungar v. Arafat*, 634 F.3d 46, 50 (1st Cir. 2011). “Failure to satisfy any one of the four requirements defeats intervention by right.” *Students for Fair Admissions, Inc. v. President and Fellows of Harvard Coll.*, 807 F.3d 472, 474 (1st Cir. 2015).

Alternatively, under Federal Rule of Civil Procedure 24(b)(1)(B), a district court may permit intervention when the putative intervenor “has a claim or defense that shares with the main action a common question of law or fact” and timely moves for intervention. Fed. R. Civ. P. 24(b)(1)(B); *Victims Rts. L. Ctr. V. Rosenfelt*, 988 F.3d 556, 561 (1st Cir. 2021). District courts enjoy broad discretion to grant or deny motions for permissive

intervention. *T-Mobile Ne. LLC v. Town of Barnstable*, 969 F.3d 33, 42 (1st Cir. 2020). Although “the court may ‘consider almost any factor rationally relevant’ to the intervention determination,” the district court at least “‘must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties’ rights.’” *Id.* at 40 (first quoting *Daggett v. Comm’n on Governmental Ethics and Election Pracs.*, 172 F.3d 104, 113 (1st Cir. 1999), and then quoting FED. R. CIV. P. 24(b)(3)).¹

A. Intervention by Right

Regarding intervention by right, I narrow my focus to Movants’ argument that Defendants cannot adequately represent their interests in this case. *T-Mobile*, 969 F.3d, 39 (starting and ending intervention by right analysis with adequacy of representation). “To demonstrate inadequate representation, a putative intervenor must show that no existing party fairly represents her interests.” *Id.* (citing *Students for Fair Admissions*, 807 F.3d at 475). In cases, like this one, where “a private party attacks a regulatory statute or administrative rule; the state or its regulators are its defendants; and other parties having an economic interest in the validity or invalidity of the statute or regulation seek to intervene,” a presumption attaches to the government’s adequacy of representation, which the movant bears the burden of overcoming with a sufficient “showing to the contrary.” *Mass. Food Ass’n v. Mass. Alcoholic Beverages Control Comm’n*, 187 F.3d 560, 566-67 (1st Cir. 1999); accord *T-Mobile*, 969 F.3d at 39 (collecting cases). The movant “must

¹ As Plaintiffs concede, there is no question that Movants satisfy the timeliness requirement. Pls.’ Mot. at 3 n.3.

produce some tangible basis” as opposed to mere speculation, to support their claim of inadequate representation. *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 207 (1st Cir. 1998).²

Movants advance two arguments that Defendants inadequately represent their interests, neither of which is convincing. First, they claim Defendants cannot adequately represent Movants’ distinct financial interests related to losses from duplicative discounts and civil penalties for noncompliance with their competing directives under two federal drug pricing laws. AbbVie Mot. at 6-8; AstraZeneca Mot. at 2-3; PhRMA Mot. at 5; Novo Nordisk Mot. at 7-9. Second, they point to Defendants’ adverse position in separate litigation against Movants concerning the statute governing the 340B pricing program as evidence of Defendants’ inadequacy to represent their interests in this case. AbbVie Mot. at 8; AstraZeneca Mot. at 2-3; PhRMA Mot. at 5-6.

As Movants explain, the Pilot Program’s rebate model is intended to resolve the competing mandates under federal drug pricing laws that threaten their financial interests. Under the current 340B discount program, Movants must offer upfront discounts at the

² Novo Nordisk’s reliance on *Berger v. N.C. State Conf. of the NAACP*, 597 U.S. 179 (2022) for the proposition that the Supreme Court disfavors the First Circuit’s presumption of adequate representation in these circumstances is misguided. Novo Nordisk Mot. at 6-7. In that case, the Supreme Court held that “a presumption of adequate representation is inappropriate when a duly authorized state agent seeks to intervene to defend a state law.” *Id.* at 197. In reaching that holding, the Court made clear its decision did “not decide whether a presumption of adequate representation might sometimes be appropriate when a private litigant seeks to defend a law alongside the government.” *Id.* Rather, the Court’s decision trained on the narrow category of “adverse presumptions” that “displace a State’s prerogative to select which agents may defend its laws and protect its interest,” a situation entirely distinct from the circumstances under which Movants seek to intervene in this case. *Id.*

point of sale to certain “covered entities,” such as Plaintiffs. AbbVie Mot. at 2; Novo Nordisk Mot. at 2. Starting on January 1, 2026, Movants will also be required to offer discounts on select drugs under Medicare as part of the Inflation Reduction Act’s Drug Price Negotiation Program, where the Secretary of Health and Human Services sets the “maximum fair price” available to certain Medicare-eligible individuals through a rebate (the “IRA discount program”). AbbVie Mot. at 2; Novo Nordisk Mot. at 2. Where these separate required discounts overlap, the IRA mandates Movants offer the lower of these two discounts. 42 U.S.C. § 1320f-2(d); Abbvie Mot. at 3; Novo Nordisk Mot. at 2-3. Consequently, Movants estimate significant financial losses in the form of duplicative discounts, once at the point of sale to covered entities under 340B and second through a rebate if those discounted drugs are later disbursed to an eligible patient under the IRA discount program. Novo Nordisk Mot. at 2-3. Movants also estimate significant financial loss from civil penalties where they fail to comply with the directive to offer the lower of the two prices. AbbVie Mot. at 3. The Pilot Program’s rebate model for 340B covered transactions, effective January 1, 2026, resolves this problem by allowing Movants to analyze claims data after the covered entity dispenses the drugs to a patient (i.e., not at the point of sale) to determine which of the two discount programs applies. AbbVie Mot. at 3-4; Novo Nordisk Mot. at 3.

Because Defendants do not face the specter of duplicate discounts and civil penalties, Movants argue Defendants cannot adequately represent their “distinctly commercial and industry-based” interests in defending the implementation of the Pilot Program. AbbVie Mot. at 7; PhRMA Mot. at 5; Novo Nordisk Mot. at 6. Movants have

invested substantial resources in anticipation of the Pilot Program’s January 1, 2026 implementation, and Defendants broader responsibilities to the public welfare cannot fully account for those interests, such that it can stand in for Movants. AbbVie Mot. at 7; PhRMA Mot. at 5; Novo Nordisk Mot. at 7-8.

Movants further assert Federal Defendants’ representation is inadequate because separate litigation between Defendants and Movants demonstrates they “often disagree[] . . . and [do] not share [Movants’] view of the 340B statute or the role that rebates may play.” AbbVie Mot. at 8. Indeed, some of the movants “are currently adverse to the government in litigation about HRSA’s claimed authority to decide whether and when manufacturers may use rebates rather than up-front discounts to effectuate the 340B price for all of a manufacturer’s drugs, not just those in the Pilot Program.” PhRMA Mot. at 5-6 (citing *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir.)). According to Movants, their divergent views on the broader statutory framework governing the 340B drug pricing scheme is evidence of Federal Defendants’ inadequacy to represent their interests in this litigation. AbbVie Mot. at 8; AstraZeneca Mot. at 2; PhRMA Mot. at 5-6.

Plaintiffs contend Movants’ reasoning is inconsistent with First Circuit caselaw. Pls.’ Opp’n at 5-6. According to Plaintiffs, simply “identifying different reasons for supporting a government program is not enough to satisfy this intervention requirement.” *Id.* at 6. Moreover, despite Movants’ representations of distinct economic interests, they ultimately “share the same objective” as Defendants: ensuring the Pilot Program goes into effect on January 1, 2026. *Id.* at 5. Finally, Plaintiffs maintain that Movants’ silence as to any additional, distinct arguments they might offer the Court in this “straightforward

administrative law case,” *id.* at 1, “that rises and falls based on the administrative record” is “near dispositive” of Defendants’ adequacy to represent Movants’ interest in this case. *Id.* at 6.

Plaintiffs also counter that Movants’ and Defendants’ adverse positions in separate litigation does not compel Movants’ assertion that Defendants cannot adequately represent their interest. As Plaintiffs explain, in separate litigation, Movants and Defendants “differ in their views on whether drug companies can unilaterally implement 340B rebate programs *without* HHS approval.” *Pls.’ Opp’n* at 6 (emphasis in original). Whereas here, both parties’ “goals are now the same.” *Id.* Movants and Defendants not only do not disagree but are “in full agreement” that Defendants have authority to implement the Pilot Program. *Id.*

The Court agrees with Plaintiffs. Even when considering Movants’ financial and adverse litigation arguments together, their position is “founded entirely on speculation” of Defendants’ inadequacy. *T-Mobile*, 969 F.3d at 40. More is required for intervention as of right. *See Students for Fair Admissions*, 807 F.3d at 475 (“putative intervenors [must] produce something more than speculation as to the purported inadequacy of representation”). Movants offer no “tangible basis to support a claim of purported inadequacy.” *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 207 (1st Cir. 1998) (citation omitted).

First, Movants’ own representations cut against their argument that Defendants are inadequately attuned to their financial interest in this case. As Movants explain, Defendants promulgated the Pilot Program “‘primarily to address’ manufacturers’ need to

‘de-duplicate’ 340B and IRA discounts.” Novo Nordisk Mot. at 3 (quoting 90 Fed. Reg. 38,165, 36,163 (Aug. 7, 2025)); *see also* AbbVie Mot. at 3 (explaining Defendants promulgated the Pilot Program because of “widespread concern about the significant compliance burdens borne by manufacturers” subject to 340B and IRA mandatory pricing schemes). Instead, this record demonstrates Defendants are aligned with Movants concerns about their dual mandates under 340B and the IRA. Movants’ unadorned assertions that Defendants’ public duty prevents them from adequately representing Movants’ industry-based interests in this lawsuit, which challenges whether a federal agency complied with its obligations under the APA, does not satisfy the Circuit’s heightened burden of persuasion for intervention by right where the government defends its own regulation. *See Daggett*, 172 F.3d at 112 (rejecting “[t]he general notion” that the government’s broader interest in representing the public “at some abstract level” demonstrates inadequate representation); *accord Rosenfelt*, 988 F.3d at 561-62 (explaining that a lack of “perfect identity of motivational interest between the movant-intervenor and the government” is not required for a finding of adequate representation) (citing *Mass. Food Ass’n*, 197 F.3d at 567); *Patch*, 136 F.3d at 207 (“the adequacy of interest requirement is more than a paper tiger”).

Second, Movants offer no evidence to suggest that their approach to defending the Pilot Program offers the Court any additional insight into the legal challenge at the heart of this lawsuit—whether Defendants complied with their statutory obligations under the APA. Movants are completely silent on “what arguments [they would] make in this Court that would otherwise be forsaken by [Defendants].” *Me. Republican Party v. Dunlap*, No.

1:18-cv-00179-JDL, 2018 U.S. Dist. LEXIS 82461, at *4 (D. Me. May 16, 2018). Instead, Movants “advocat[e] for the general validity and enforcement of” the challenged agency action, “and it appears that both parties would have the same approach.” *Id.* (citing *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 539 (1972)). There is nothing in any of Movants’ motions suggesting they “would inject some missing ingredient into [Defendants’] defense,” nor do they identify any arguments Defendants are unlikely to advance absent their intervention, such that Federal Defendants’ defense would be inadequate to protect Movants’ interests. *T-Mobile*, 969 F.3d at 40. Plaintiffs’ complaint alleges five violations of the APA against Federal Defendants, but Movants fail to state how their participation as a party would illuminate the administrative record on which this case turns entirely. *Compl.* ¶¶ 130-175.

Finally, the adverse positions between Movants and Defendants in separate 340B litigation is insufficient to rebut the presumption against adequate representation. Again, Movants’ own representations undermine their position. As PhRMA explains, some of its members “are currently adverse to the government in litigation about HRSA’s claimed authority to decide whether and when manufacturers may use rebates rather than up-front discounts to effectuate the 340B price for all of a manufacturer’s drugs, not just those in the Pilot Program.” PhRMA Mot. at 5-6 (citing *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir.)). However, that litigation concerns Movants’ position that they can fulfill their 340B discount requirements by issuing rebates rather than upfront discounts without prior agency approval. Nothing from Movants’ description of that litigation indicates that they are misaligned with Defendants on whether Defendants may promulgate

the Pilot Program in this case. Indeed, the parties' divergent positions on whether the 340B statute, 42 U.S.C. § 256b(a)(1), authorizes pharmaceutical manufacturers to determine unilaterally how covered entities receive their discounted drugs does not suggest Defendants will not vigorously defend that their promulgation of the Pilot Program complied with their statutory obligations under the APA. In other words, Movants fail to demonstrate that, despite their adverse positions in separate litigation, they are not entirely aligned with Defendants' position in this administrative law action under the APA, where both Movants and Defendants maintain the agency action is lawful, and Movants offer no evidence that Defendants are not "zealously interested in upholding the validity" of the agency action. *Mass. Food Ass'n*, 197 F.3d at 567; *see also Dunlap*, 2018 U.S. Dist. LEXIS 82461, at *4 (rejecting movant-intervenor's argument that adverse positions in a separate related lawsuit renders the government an inadequate representative where both "advocat[e] the general validity and enforcement" of the challenged government action).

Accordingly, because Movants fail to demonstrate that Defendants cannot adequately represent their interests, the Court finds that Movants are not entitled to intervene as of right. The Court's analysis need go no further. *Students for Fair Admissions*, 807 F.3d at 474 ("Failure to satisfy any one of the four requirements defeats intervention by right").

B. Permissive Intervention

Under Rule 24(b)(1)(B) this Court may, in its discretion, allow the intervention of any party who "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1)(B). "When deciding whether or not to allow

permissive intervention,” the Court ““must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties’ rights.”” *T-Mobile*, 969 F.3d at 40. Additionally, the Court may “consider almost any factor rationally relevant” to the proposed intervention. *Daggett*, 172 F.3d at 113.

Particularly relevant here is the Court’s “denial of intervention as of right based on an intervenor’s failure to overcome the presumption of adequate representation by the government,” which “cuts against [Movant’s] case for permissive intervention.” *Dunlap*, 2018 U.S. Dist. LEXIS 82461, at *5 (citing *Tutein*, 43 F. Supp. 2d at 131). The First Circuit is clear that “a district court considering requests for permissive intervention should ordinarily give weight to whether the original parties to the action adequately represent the interests of the putative intervenors.” *T-Mobile*, 969 F.3d at 41 (citing *Kowal v. Malkemus (In re Thompson)*, 965 F.2d 1136, 1142 n.10 (1st Cir. 1992)); *Rosenfelt*, 988 F.3d 556 at 564 (same); *Mass Food Ass’n*, 197 F.3d at 568 (same). Thus, although in this early stage of litigation, and notwithstanding the Pilot Program’s fast-approaching January 1, 2026 implementation date, the Court does not believe that Movants’ intervention necessarily will *immediately* unduly delay or prejudice the proceedings. However, looking beyond January 1, it is possible that intervention would create undue delay in the final disposition of this case involving an important administrative program. That concern, amplified by Movants’ failure to demonstrate how they might “add any missing element” to Federal Defendants’ defense of the agency action, leads the Court to deny Movants’ request for permissive intervention. *T-Mobile*, 969 F.3d at 40.

C. Amicus Status

Although Movants may not intervene in this case as parties, I will permit them to participate as amici curiae. Participation as amici satisfies Movants' interest in "provid[ing] information regarding the severe harm that would befall the Manufacturers if the program were enjoined, or the efforts the Manufacturers have undertaken [to] prepare for the program's implementation date." *Novo Nordisk Mot.* at 9; *accord Rosenfelt*, 988 F.3d at 564; *Mass. Food Ass'n*, 197 F.3d at 568; *Students for Fair Admissions, Inc. v. President and Fellows of Harvard Coll.*, 308 F.R.D. 39, 52 (D. Mass. 2015).

CONCLUSION

For the foregoing reasons, the Court DENIES AbbVie Inc.'s and Pharmacyclics LLC's Motion to Intervene (ECF No. 36), AstraZeneca Pharmaceuticals LP's Motion to Intervene (ECF No. 39), Pharmaceutical Research and Manufacturers of America Motion to Intervene (ECF No. 45), and Boehringer Ingelheim Pharmaceuticals, Inc.'s and Novo Nordisk Inc.'s Motion to Intervene (ECF No. 50). However, the Court GRANTS Movants leave to proceed as amici curiae, and the Court will consider their briefs in opposition to Plaintiffs' motion (ECF Nos. 72, 73) as amicus briefs.

SO ORDERED.

Dated this 18th day of December, 2025.

/s/ Lance E. Walker
CHIEF U.S. DISTRICT JUDGE